REMARKS

Abstract

Applicants hereby confirm that the Abstract referred to by the Examiner in the present Office Action is the intended Abstract.

Specification

The Examiner has objected to the preliminary amendment filed June 15, 2000, under 35 U.S.C. 132 for purportedly introducing new matter into the disclosure. The Examiner states that the added material, which is purportedly not supported by the original disclosure, is the inclusion of bicarbonate in Claims 48, 59, 70, 82 and any dependent claims. Without acceding to the Examiner's objection to the preliminary amendment under 35 U.S.C. 132, Applicants have deleted the term "bicarbonate" from Claims 48, 59, 70 and 82. Therefore, the Examiner's objection to the preliminary amendment under 35 U.S.C. 132 is now deemed moot.

Claim Rejections - 35 USC Section 112

The Examiner has rejected Claim 48 under 35 USC §112, first paragraph, for purportedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Without acceding to the Examiner's rejection of Claim 48 under 35 USC §112, first paragraph, Applicants have deleted the term "bicarbonate" from Claim 48. Therefore, the Examiner's rejection of Claim 48 under 35 USC §112, first paragraph, is now deemed moot.

Response to Arguments

The withdrawal of the Examiner's rejection of Claims 38-44 under 35 U.S.C. 103(a) with respect to Seyffart *et al.* (US 4,879,280) and Breborowicz *et al.* (EP 0 555 087 A1) in view of "Textbook of Biochemistry" is hereby acknowledged.

The Examiner states the following:

> However, it is noted that applicant's statements with respect to the claimed oligomers having the "same repeating monosaccharide" is not supported by the specification. Furthermore, such a feature is not claimed. As such, the references may be reconsidered if examination is extended to aminosugars beyond the elected species of N-acetylglucosamine.

Applicants disagree with the Examiner's statement that oligomers having the same repeating monosaccharide is not supported by the specification. Applicants respectfully submit that this feature is fully supported in the specification as originally filed on page 4, line 23, to page 5, line 12, and page 6, lines 21 to 35. In particular, page 4, line 23, to page 5, line 12, provide the following:

> In order for NAG and related amino sugars to be useful as osmotic agents in CAPD solutions they must have a high chemical purity similar to that which would be required for use in pharmaceutical products, which means a minimum purity of 98.5%. NAG which is of this purity can be manufactured by two methods. The first is the acid digestion of crude chitin, which is a linear polymer of repeating units of NAG obtained from crab and shrimp shells and other crustaceans, followed by isolation of the deacetylation of the individual NAG units to glucosamine. The glucosamine is isolated an crystallized to a high level of purity and then is reacetylated using acetic anhydride to N-acetylglucosamine, which is precipitated and recrystallized from alcohol, such that its purity is greater than 98.5%. The second method of manufacturing NAG, and the preferred method, is to obtain NAG from dried crustacean shell or crude chitin by direct enzymatic digestion with an ensemble of enzymes including chitinase and chitobiase, which degrades the chitin polymer of NAG into disaccharide units of chitobiase and then into monomer units of NAG directly, without having to undergo any organic synthetic step. The NAG is recrystallized from alcohol to a high degree of purity from ethanol. The enzymes required for this process are secreted into the growth media of various microorganisms, especially Serratia marcescens. Thus this method of manufacture not only provides NAG of a suitable purity for use in CAPD solutions but also permits the relatively inexpensive production of NAG as the chitin or crustacean shells can be added directly to the cell-free growth medium from a culture of S. marcescens and the NAG readily isolated from the medium after a suitable reaction period. By varying the length of the enzymatic reaction time the production of polymers of varying units of NAG can be produced, which can be further refined and isolated as specific molecular weight entities by way of separation using available chromatographic techniques, and which can be isolated, crystallized and further purified by recrystallization using methods familiar to those skilled in the methods of carbohydrate chemistry isolation and purification.

And page 6, lines 21 to 35, provide the following:

> The CAPD solution of this invention is intended to provide similar electrolyte levels as currently available CAPD solutions, except that the osmotically active carbohydrate composition is different, being composed of acetylated and deacetylated amino sugars including N-acetylglucosamine, glucosamine, N-acetylgalactosamine, galactosamine, N-acetylmannosamine, mannosamine each alone, or in combination at varying concentrations or with varying concentrations of glucose, or oligomers of N-acetylglucosamine, N-acetylmannosamine, N-galactosamine, galactosamine, mannosamine, and glucosamine such that they are comprised of at least 2 carbohydrate units and not more than 12 units. The composition may be a mixture of oligomers of varying amounts of each oligomer either alone or in combination with each other. As well the CAPD solutions of this patent may contain additional osmotically active agents in varying proportions to the acetylated and deacetylated amino sugars such acidic carbohydrates which are also incorporated into the tissue glycosoamioglycans (GAG's) such as glucuronic acid and iduronic acid.

The Examiner has rejected Claim 48 under 35 U.S.C. 103(a) as being unpatentable over Kubo *et al.* (JP 11-71273-A) for reasons as stated previously. Applicants have amended Claim 48 by removing the term "bicarbonate" therefrom. Therefore, the Examiner's rejection of Claim 48 under 35 U.S.C. 103(a) is now deemed moot.

Claim Rejections - 35 USC Section 102

The Examiner has rejected Claims 38-43 under 35 U.S.C. 102(b) as being anticipated by Pecht *et al.* (US Pat. 4,996,296). The Examiner states the following:

> Pecht discloses a 5% N-acetylglucosamine solution in aqueous buffer (see col. 18, lines 45-50 and col. 16, lines 20-25). The preamble and the intended use of the instant claims are not given patentable weight. The limitations of the instant claims are the presence of N-acetylglucosamine as the elected species of amino sugar in an effective amount, which is claimed as ranging from about 0.5% to about 5% to about 5% (w/v). The reference meets these limitations.

The Examiner has rejected Claims 38-43 under 35 U.S.C. 102(b) as being anticipated by Speck (US Pat. 4,870,061). The Examiner states the following:

> Speck discloses aqueous solutions of N-acetylglucosamine having a concentration of 5 to 55 mg/mL, corresponding to 0.5 to 5.5% (w/v) (see col. 4, lines 50-52). The preamble and the intended use of the instant claims are not given patentable weight. The limitations of the instant claims are the presence of N-acetylglucosamine as the elected species of amino sugar in an effective amount, which is claimed as ranging from about 0.5% to about 5% (w/v). The reference meets these limitations.

Applicants respectfully submit that they disagree with the Examiner's conclusion. Applicants submit that none of Pecht *et al.* or Speck or any other prior art reference teach the claimed invention. Applicants respectfully submit that the Examiner has not established the *prima facie* case of anticipation. Applicants will show that not all elements of *prima facie* anticipation have been met. The Federal Circuit endorsed this view in *In re Oetiker* (977 F.2d., 24 USPQ 2d 1443 (Fed. Cir. 1992)), stating that "if the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent" (*Id*, 24 USPQ 2d at 144).

In *W.L. Gore & Associates v. Garlock, Inc.*, the Federal Circuit stated that "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration" (*W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540, 220 USPQ at 313 (citing *Soundscriber Corp. v. United States*, 360 F.2d 954, 960, 148 USPQ 298, 301 (Ct. Cl.), *adopted*, 149 USPQ 640 (Ct. Cl. 1966)). See also *Carella v. Starlight Archery*, 804 F.2d 135, 138, 231 USPQ 646 (Fed. Cir.), *modified on reh'g*, 1 USPQ 2d 1209 (Fed. Cir. 1986); *RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 1444,

221 USPQ 385, 388 (Fed. Cir. 1984)). It is not enough, however, that the prior art reference disclose all the claimed elements in isolation. Rather, as stated by the Federal Circuit, "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim" (*Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added)). The Federal Circuit has indicated that "[i]n deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference" (*Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ at 485).

The Federal Circuit has added that the anticipation determination is viewed from one of ordinary skill in the art: "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention" (*Scripps Clinic & Research Found. v. Genentech Inc.*, 927 F.2d 1565, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991)).

Similarly, the Federal Circuit has stated:

> An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention.

(*ATD Corp. v. Lydall, Inc.*, 159 F.3d, 534, 48 USPQ 2d 1321, 1328 (Fed. Cir. 1998) (citing *In re Spada*, 911 F.2d 705, 708, 15 USPQ 2d 1655, 1657 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 678, 7 USPQ 2d 1315, 1317 (Fed. Cir. 1988)).

By combining the elements of these various decisions, one can see that a prima facie case of anticipation is established when the Examiner provides:

1. a single reference
2. that teaches or enables

3. each of the claimed elements (arranged as in the claim)

4. expressly or inherently

5. as interpreted by one of ordinary skill in the art.

Accordingly, an Applicant who is able to prove that any one of these elements is not present will effectively prevent the prima facie case of anticipation from being established. Applicants herein provide the following in respect of the Examiner's purported prima facie case of anticipation:

Element 2: Reference That Teaches or Discloses

The second element of prima facie anticipation requires that the reference, under any of the subsections of Section 102, teach. That is, the reference must generally place the needed subject matter supporting the anticipation rejection in the public domain before the date of invention (i.e., generally before the filing date of the application) (*In re Zenitz*, 333 F.2d 924, 142 USPQ 158, 160 (C.C.P.A. 1964)). Thus, the second element contains two main requirements for a reference to support an anticipation rejection: (1) the reference must disclose the claimed invention, and (2) it must be available to the public (See, e.g., *Innovative Scuba Concepts Inc. v. Feder Indus.*, 819 F. Supp. 1487, 27 USPQ 2d, 1254, 1263 (D. Colo. 1993) ("Description by a prior publication occurs where the work adequately describes the invention in question and the work qualifies as a 'printed publication'.")).

Because the prior art is required to teach, the Examiner must provide a reasonable basis for stating that a prior art reference under subsection 102(b) sufficiently describes the subject matter therein to place the subject matter in the public domain. Thus, if an Examiner's assertion that the reference adequately describes the subject matter to place it in the public domain is unreasonable, an Applicant can attack this element of anticipation to prevent the prima facie case of anticipation. If the reference does not teach, no anticipation can be found.

Applicants' Inventi n

Applicants' application discloses and claims the following:

> 38. A peritoneal dialysis solution comprising at least one amino sugar in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from a patient's blood across the peritoneal membrane of the patient into the solution.

The peritoneal dialysis solutions disclosed and claimed in the present invention are significantly different from the prior art peritoneal dialysis solutions in that the osmotically active agent is different. The osmotically active agent of the prior art peritoneal dialysis solutions is normally glucose, whereas the osmotically active agent of the presently disclosed and claimed peritoneal dialysis solutions is at least one amino sugar. As a result, the peritoneal dialysis solutions disclosed and claimed in the present invention:

1. are more biocompatible with the peritoneal membrane and thus preventing or slowing down the morphologic and functional deterioration of the peritoneal membrane and extending the time over which patients may effectively use CAPD treatment,

2. provide a lower rate of peritoneal infection for patients receiving peritoneal dialysis treatment,

3. provide a lesser risk of cardiovascular disease due to a reduction in the lipid changes typical of use of currently available peritoneal dialysis solutions, and

4. provide a reduction of protein and albumin loss into dialysate effluent in chronic peritoneal dialysis situation leading to higher serum albumin levels which is highly correlated with reduction of mortality on peritoneal dialysis,

<u>while providing the necessary osmotic effect required in peritoneal dialysis</u>. Applicants have discovered that this is accomplished by the inclusion of at least one amino sugar, such as, for example, acetylated amino sugars (in one embodiment N-acetylglucosamine) and/or deacetylated amino sugars in a peritoneal dialysis solution at a concentration of between about 0.5 to about 5% (w/v). This peritoneal

dialysis solution is totally unexpected to persons skilled in the art having regard to the teachings in the prior art. No one piece of prior art alone or combined teaches the peritoneal solutions as taught and claimed by Applicants in the present application.

Teachings of United States Patent Nos. 4,996,296 and 4,870,061 to Pecht *et al.* and Speck, respectively

Applicants submit that Pecht *et al.* teach an N-acetylglucosamine solution in buffer wherein the buffer consists of BBS-Ca^{2+} containing 0.5% Triton X-100 and 0.15% soybean lipids. This N-acetylglucosamine solution in buffer is an eluent that is used to elute lectin affinity columns in the purification of cromolyn binding protein.

Applicants submit that Speck teaches aqueous solutions of N-acetylglucosamine in aqua pro injectione for the intraarticular, intravenous and intramuscular injection or for oral or buccal application for the treatment of degenerative diseases of the joints and connective and supporting tissues thereof. Speck further teaches that the osmolality of the solutions has to be adapted to the physiological osmotic pressure.

Differences between Applicants' Invention and the Teachings of Pecht *et al.* and Speck

Applicants respectfully submit that the Examiner's assertion that Pecht *et al.* or Speck adequately describes the subject matter of the present invention to place it in the public domain is unreasonable. The Pecht *et al.* or Speck reference does not teach a "peritoneal dialysis" solution at all, let alone a "peritoneal dialysis" solution as disclosed and claimed in the present application.

Applicants respectfully submit that the preambular limitation "a peritoneal dialysis" solution in the claims of the present invention gives patentable weight to said claims. Applicants wish to bring the following statements of the law, as they apply to Applicants' invention in respect of claim preambles, to the Examiner's attention:

There is no single, definitive test as to when the preamble limits a claim. As stated by the Federal Circuit in *Corning Glass Works v. Sumitomo Elec. U.S.A. Inc.*, 868 F.2d 1251, 9 USPQ 2d 1962, 1966 (Fed. Cir. 1989):

> The effect preamble language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.

Its significance is determined on the basis of the facts in each case. *In re Duva* (CCPA 1967) 387 F2d 402, 156 USPQ 90. That is, the specification should be examined to determine whether the inventor intended such language to represent an additional structural limitation or mere introductory language. *In re Stencel*, 828 F.2d 751, 754, 4 USPQ 2d 1071, 1073 (Fed. Cir. 1987).

As the Federal Circuit has stated in *Bell Communications Research v. Vitalink Communications Corp.*, 55 F.3d 615, 34 USPQ 2d 1816, 1819-20 (Fed. Cir. 1995):

> a claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use *both* the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects.

Only a review of the entirety of the patent to understand what the inventors actually invented and intended to encompass by the claim can resolve whether

preamble recitations are structural limitations or mere statements of purpose or use. The inquiry involves examination of the entire patent record to determine what invention the patentee intended to define and protect.

Where the preamble is essential to point out the claimed invention and give meaning and vitality to the claim, it is given the effect of a limitation. *Diversitech Corp. v. Century Steps Inc.* (CAFC 1988) 850 F2d 675, 7 PQ2d 1315; *In re Bulloch et al.* (CCPA 1979) 604 F2d 1362, 203 USPQ 171 (**stable color developer concentrate**); *In re Szajna et al.*, (CCPA 1970) 422 F2d 443, 164 USPQ 632; *In re Walles et al.* (CCPA 1966) 366 F2d 786, 151 USPQ 185 ("**a composition for setting hair**"); *Smith v. Bousquet* (CCPA 1940) 111 F2d 157, 45 USPQ 347 (**insecticide composition**); *Ex parte Varga* (POBA 1973) 189 USPQ 204; *In re Tuominen* (CCPA 1982) 671 F2d 1359, 213 USPQ 89 (**sunscreen composition**).

According to *Kropa v. Robie et al.* (CCPA 1951) 187 F.2d 150, 88 USPQ 478:

> in those ... cases where the preamble to the claim ... was expressly or by necessary implication given the effect of a limitation, the introductory phrase was deemed essential to point out the invention defined by the claim or count. In the latter class of cases, the preamble was considered necessary to give life, meaning and vitality to the claims.

If the claim preamble, when read in the context of the entire claim, recites limitations of the claims, or if the claim preamble is "necessary to give life, meaning, and vitality" to the claim, then the claims preamble should be construed as if in the balance of the claims. *Pitney Bowes Inc. v. Hewlett-Packard Co.* (CAFC 1999) 51 USPQ 2d 1161.

In the claims of the present invention, the preamble is "necessary to give life, meaning and vitality" to the claims. The preamble statement that the patent claims a "peritoneal dialysis" solution is not merely a statement describing the invention's intended field of use. Instead, that statement is intimately meshed with the ensuing language in the claim.

Further, the Pecht *et al.* or Speck reference does not teach that the N-acetylglucosamine is present in the solution "<u>in an effective amount sufficient to</u>

create an osmotic pressure to effect the removal of water by diffusion from a patient's blood across the peritoneal membrane of the patient into the solution" as disclosed and claimed in the present application.

The claims of the present invention are written in functional form. In this situation, the elements of the claims of the present invention are defined not only with respect to their structural interaction, but also with respect to each element's intended function. Thus, the claims define the function of the particular element. Applicants respectfully submit that the functional language "in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from a patient's blood across the peritoneal membrane of the patient into the solution" in the claims of the present invention give patentable weight to said claims. Applicants wish to bring the following statements of law, as they apply to Applicants' invention in respect of functional language, to the Examiner's attention:

As stated by the CCPA:

> We take the characterization "functional", as used by the Patent Office and argued by the parties, to indicate nothing more than the fact that an attempt is being made to define something (in this case, a composition) by what it *does* rather than by what it *is* (as evidenced by specific structure or material, for example). In our view, there is nothing intrinsically wrong with the use of such a technique in drafting patent claims. Indeed we have even recognized in the past the practical *necessity* for the use of functional language.[1]

Applicants respectfully submit that an Examiner is not permitted to dissect the claim and remove the functional limitations before determining anticipation. For example, in *In re Land*,[2] the CCPA noted that portions of a claim were functional, but nevertheless held the claim patentable over the prior art in view of the functional limitations:

> It is true that the italicized portions [of claim 70] are "functional" but we do not regard that as good ground to give them "no weight" in view of the third paragraph [currently the sixth paragraph] of 35 U.S.C. 112. We give them weight and with this limitation we think claims 70 and 71 are limited to deferred diffusion *built into the*

---

[1] *In re* Swinehart, 439 F.2d 210, 169 USPQ 226, 228-29 (C.C.P.A. 1971) (footnote omitted).

[2] *In re* Land, 368 F.2d 866, 151 USPQ 621 (C.C.P.A. 1966).

> *structure recited*, thereby being limited to the actual invention disclosed and hence allowable for the same reasons given by the board . . . .[3]

There is ample precedent to establish that functional limitations are appropriate in claims and should be afforded patentable weight by the Examiner for determining anticipation.[4] Accordingly, Applicants respectfully submit that they should not accept the Examiner's position that certain limitations recited in a claim are functional and therefore not patentable. Functional limitations are to be given patentable weight even if it is only these limitations that distinguish over the prior art.

The Federal Circuit has interpreted functional language in an apparatus claim as requiring that an accused apparatus possess the capability of performing the recited function.[5] However, the Federal Circuit has never determined that functional language in a claim automatically converts an apparatus claim into a method of use or hybrid claim.[6]

---

[3] *Id.*, 151 USPQ at 635-36 (emphasis in original).

[4] *See, e.g., In re* Ludtke, 441 F.2d 660, 169 USPQ 563, 566 (C.C.P.A. 1971) ("We agree with the Patent Office that the spatial separation between the panels is recited in functional language; however, as we said recently *In re* Swinehart, . . . there is nothing intrinsically wrong with the use of such claim language."); *In re* Atwood, 354 F.2d 365, 148 USPQ 203, 210 (C.C.P.A. 1966) ("We have here a combination claim and the limitations ignored by the Board as use limitations we think are functional expressions which must be given weight."); *In re* Bisley, 197 F.2d 355, 94 USPQ 80, 83 (C.C.P.A. 1952):

> It appears to us that these claims define the angle of the pivot pin with respect to component elements of the mixer, albeit by geometrical language, in such a manner that the pin is structurally located, by the terms of these claims, at a substantial angle with respect to identified horizontal and vertical datum planes and within that range of angularity which will achieve appellant's desired novel result. Definite limitations in a claim should not be ignored or construed out of the claim.

See also Ex parte Sherman, 45 USPQ 532, 534 (Pat. Off. Bd. App. 1939):

> While the claims contain numerous functional statements, these statements seem to be used for the purpose of clearly defining or differentiating elements which have been positively included in the claims. We see no objection to the use of the functional statement to define an element, even where the element may be set forth by the term "means".

[5] Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 832, 20 USPQ 2d 1161, 1171 (Fed. Cir. 1991).

[6] R.A.C.C. Indus., Inc. v. Stun-Tech, Inc., Civ. App. 98-1186, slip op. at 7 (Fed. Cir. Dec. 2, 1998) (unpublished).

The claims of the present application differ from the teachings of Pecht *et al.* or Speck because the claims of the present application are directed to a peritoneal dialysis solution. As discussed above, Pecht *et al.* is directed to an N-acetylglucosamine solution in buffer consisting of BBS-Ca2+ containing 0.5% Triton X-100 and 0.15% soybean lipids which is used as an eluent to elute lectin affinity columns. The N-acetylglucosamine solution in buffer taught in Pecht *et al.* would not be interpreted by a person skilled in the art to be suitable for performing peritoneal dialysis. Speck is directed to aqueous N-acetylglucosamine solutions in aqua pro injectione for the intraarticular, intravenous or intramuscular injection for the treatment of degenerative diseases of the joints. Further, the osmolality of the aqueous N-acetylglucosamine solutions of Speck must be adapted to the physiological osmotic pressure. Since a peritoneal dialysis solution must have a greater osmolarity than the blood to be effective, the aqueous N-acetylglucosamine solutions of Speck would not be interpreted by persons skilled in the art to be suitable for performing peritoneal dialysis.

Thus, having regard to the claims of the present application, Applicants submit that the Pecht *et al.* or Speck reference does not teach Applicants' invention. The Pecht *et al.* or Speck reference does not teach a peritoneal dialysis solution at all, let alone a peritoneal dialysis solution comprising at least one amino sugar in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from a patient's blood across the peritoneal membrane of the patient into the solution, as fully disclosed and claimed in the present application. Applicants are of the opinion that the preambular statement "a peritoneal dialysis solution" and the functional language "in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from a patient's blood across the peritoneal membrane of the patient into the solution" in the claims of the present application is sufficient to overcome the rejection of the Examiner under 35 U.S.C., Section 102(b).

Therefore, Applicants respectfully submit that the Pecht *et al.* or Speck reference is irrelevant. Since Pecht *et al.* or Speck does not teach, no anticipation can be found.

Element 3: Each of the Claimed Elements

According to the Federal Circuit, "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration" (*W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983) (citing *Soundscriber Corp. v. United States*, 360 F.2d 954, 960, 148 USPQ 298, 301 (Ct. Cl.), *adopted*, 149 USPQ 640 (Ct. Cl. 1966)), *cert. denied*, 469 U.S. 851 (1984). See also *Carella v. Starlight Archery*, 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed. Cir.), *modified on reh'g*, 1 USPQ 2d 1209 (Fed. Cir. 1986); *RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984)). It is not enough, however, that the reference disclose all the claimed elements in isolation. Rather, as stated by the Federal Circuit, the prior art reference must disclose each element of the claimed invention "*arranged as in the claim.*"[7] Thus, even if the prior art reference includes all the elements that are claimed, if the arrangement of the claimed elements is different from the arrangement of the prior art elements, anticipation will not be present.

Anticipation will not be found in a situation where the claimed elements are arranged differently in the prior art. Further, anticipation will not be found when the prior art is lacking or missing a specific feature or the structure of the claimed invention. Additional prior art is therefore necessary to show the specific arrangement or structure of the claimed invention when novelty is present. Because more than one reference is required to establish unpatentability of the claimed invention in such a situation, anticipation under Section 102 cannot be found, and validity is determined in terms of obviousness under Section 103 (*Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 20 USPQ 2d 1746, 1748 (Fed. Cir. 1991)).

The Examiner must provide a reasonable basis that the prior art reference under subsection 102(b) contains the claimed subject matter as arranged in the claim of the application. Thus, if an Examiner's assertion that the reference contains all

---

[7] Lindermann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added).

elements of the claimed subject matter is unreasonable, an Applicant can attack this element of anticipation to prevent the prima facie case of anticipation.

Applicants respectfully submit that the Examiner's assertion that the Pecht *et al.* or Speck reference contains all of the elements of the claimed subject matter is unreasonable. As discussed above, Applicants claim the following:

> 38. A peritoneal dialysis solution comprising at least one amino sugar in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from a patient's blood across the peritoneal membrane of the patient into the solution.

As discussed above, the Pecht *et al.* or Speck reference does not teach a peritoneal dialysis solution at all, let alone a peritoneal dialysis solution having the desired structure and utility as fully disclosed and claimed in the present application. Therefore, the Pecht *et al.* or Speck reference is clearly lacking or missing the claimed subject matter as arranged in the claim of the application, and thus, anticipation cannot be found.

Element 4: Expressly or Inherently

The Federal Circuit has cautioned that all claimed elements must be found in the prior art for anticipation to be found. As stated by the Federal Circuit:

> For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. ... Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there.

(*Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 43 USPQ 2d 1481, 1490 (Fed. Cir. 1997)).

Applicants respectfully submit that not all of the claimed elements of the present application are found in the Pecht *et al.* or Speck reference. As mentioned above, the N-acetylglucosamine solution in buffer of the Pecht *et al.* reference or the aqueous N-acetylglucosamine solution in aqua pro injectione of the Speck reference does not teach a peritoneal dialysis solution at all let alone a peritoneal dialysis solution as disclosed and claimed in the present application. Therefore, the claims of the present invention are not taught by the Pecht *et al.* or Speck reference, either explicitly or implicitly. Since not all of the claimed elements of the present application are found in the Pecht *et al.* or Speck reference, anticipation cannot be found.

Element 5: Interpreted by One of Ordinary Skill

The last element of prima facie anticipation requires that the prior art reference relied on be interpreted by one of ordinary skill in the art. The prior art must be such that a person of ordinary skill in the field of the invention would consider there to be no difference between the claimed invention and the reference disclosure (*Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991)). In other words, the prior art reference must put the claimed invention in the hand of one skilled in the art (*In re Donohue*, 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed. Cir. 1985)). As stated by the CCPA:

> Our study of the prior cases ... indicates that the proper test of a description in a publication ... requires a determination of whether one skilled in the art to which the invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought.

(*In re LeGrice*, 301 F.2d 929, 939, 133 USPQ 365, 373-74 (C.C.P.A. 1962)). The Federal Circuit has subsequently added that "the [prior art] reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it" (*In re Spada*, 911 F.2d 705, 708, 15 USPQ 2d 1655, 1657 (Fed. Cir. 1990) (citations omitted)).

The hypothetical person of ordinary skill is not defined as one who is deemed to be aware of all relevant prior art or literature.[8] Rather, the hypothetical person of ordinary skill is defined by considering the educational level of the inventor, the types of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of workers in the field.[9] Once the person of ordinary skill has been defined, then a determination may be made as to whether that person of ordinary skill would have been familiar with the relevant literature, if such a

---

[8] Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 54 USPQ 2d 1299, 1304 (Fed. Cir. 2000).

[9] Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962, 1 USPQ 2d 1196, 1201 (Fed. Cir. 1986).

consideration is appropriate when attempting to define the patent claims or the prior art.

In constructing a rejection based on anticipation, the Examiner must identify the elements of the claims of the application, determine their meaning in light of the specification and prosecution history, and identify the corresponding elements disclosed in the allegedly anticipating reference (*Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984)). Accordingly, when the reference relied on is subject to more than one interpretation, it is the interpretation of one of ordinary skill that is to be followed.

Thus, an Applicant can attack an Examiner's interpretation of a prior art reference as being flawed if the Applicant can show the Examiner is not interpreting the reference as would one of ordinary skill in the art.

In this regard, Applicants submit that the Pecht *et al.* or Speck reference does not describe the claimed invention such that one of ordinary skill in the art could have made the claimed invention. For the Pecht *et al.* or Speck reference to anticipate Applicants' claimed invention, it must disclose all of the elements of the claimed invention or their equivalents functioning in essentially the same way which Applicants submit the Pecht *et al.* or Speck reference does not. As discussed above, the Pecht *et al.* or Speck reference does not teach a peritoneal dialysis solution at all, let alone a peritoneal dialysis solution as disclosed and claimed in the present application. If the N-acetylglusosamine solution in buffer of the Pecht *et al.* reference or the aqueous N-acetylglucosamine solution in aqua pro injectione of the Speck reference was used as a peritoneal dialysis solution, it would fail as discussed above. The solution of the Pecht *et al.* or Speck reference is not a peritoneal dialysis solution. A person skilled in the art would consider there to be considerable unobvious differences between the claimed invention and that of the Pecht *et al.* or Speck reference. Thus, the Examiner is not interpreting the Pecht *et al.* or Speck reference as would one of ordinary skill in the art. Therefore, anticipation cannot be found.

Applicants respectfully submit that they have, in proving that the above elements of the Examiner's prima facie case of anticipation are not present, effectively prevented the prima facie case from being established. The claims are clearly new, useful and inventive. Therefore, reconsideration of the Examiner's rejection of Claims 38-43 under 35 USC §102(b) is respectfully requested.

There is no reason to doubt the novelty of the teachings and claims of the present application. The peritoneal dialysis solution of the present application represents considerable progress in the field of peritoneal dialysis technology.

Thus, in view of the above arguments, Applicants have addressed all of the issues raised by the Examiner in the Official Action dated February 26, 2003, and respectfully submit that they have overcome the rejections relating to 35 USC §102(b).

Therefore, in light of the above, reconsideration is respectfully requested of Claims 38-43.

Claim Rejections - 35 USC Section 103

The Examiner has rejected Claims 44-47 under 35 USC 103(a) as being unpatentable over Speck (US 4,870,061).

The Examiner states:

> Speck teaches aqueous solutions of N-acetylglucosamine having a concentration of 5 to 55 mg/mL, corresponding to 0.5 to 5.5% (w/v) (see col. 4, lines 50-52). Speck further teaches that the osmolality of the solutions has to be adapted to the physiological osmotic pressure by addition of NaCl or glucose (see col. 4, lines 50-60). The reference lacks examples with both glucose and sodium.
>
> The missing ingredients of glucose and sodium have art-recognized suitability for the intended purpose of formulating a composition adapted to physiological osmotic pressure. The selection of a known material based on its suitability for its intended use has been determined to be prima facie obvious. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945); *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960); and MPEP 2144.07. Furthermore, differences in concentration will not support the patentability of subject matter encompassed b the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).
>
> It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of Speck by the use of glucose and sodium to modify the osmolality in order to formulate a composition for physiological administration. The motivation for the change comes from the teaching by Speck that "the osmolality of the solutions...has to be adapted to the physiological osmotic pressure by addition of for instance NaCl or glucose".

Applicants respectfully submit that they disagree with the Examiner's conclusion. Applicants submit that the Speck reference, alone, or any combination of the Speck reference with the knowledge of a person skilled in the art, would not render the claimed invention obvious. Applicants respectfully submit that the Examiner has not established the prima facie case of obviousness. Applicants will show that the Examiner has not demonstrated all elements of the prima facie case, and therefore, in Applicants' respectful submission, the Examiner's opinion of obviousness is deficient and Applicants are deserving of a patent. The Federal Circuit has endorsed this view in *In re* Oetiker (977 F.2d 1443, 24 USPQ 2d 1443 (Fed. Cir. 1992)), stating that "if the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." (*Id.*, 24 USPQ 2d at 1444).

For example, an early relevant expression was stated by the CCPA as follows:

> In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed substitution, combination or other modification.[10]

The CCPA has subsequently added that the prima facie case requires that the reference teachings "appear to have suggested the *claimed subject matter*."[11] Thus, the Examiner must explain why the prior art would appear to show the claimed subject matter and not simply the general aspects of the invention. Further, the Federal Circuit has added that when more than one reference or source of prior art is required in establishing the obviousness rejection, "it is necessary to ascertain whether the prior art teachings would appear to be sufficient to one of ordinary skill in the art to suggest making the claimed substitution or other modification."[12] Thus, it is not enough that the Examiner present references that contain the assorted features of the invention. The Examiner must also show why it "would appear" that the references would have been combined.[13]

---

[10] *In re* Lintner, 458 F.2d 1013, 173 USPQ 560, 562 (C.C.P.A. 1972). *See also In re* Fielder, 471 F.2d 640, 176 USPQ 300, 302 (C.C.P.A. 1973). For anticipation rejections, the CCPA has stated the following:

> Simply stated, a prior publication or patent description will be considered as anticipatory when its disclosure is at once specific and enabling with regard to the particular subject matter at issue. In effect, a prima facie case is made out whenever a reference is shown to contain a disclosure which is specific as to every critical element of the appealed claims.

In re Wilder, 429 F.2d 447, 166 USPQ 545,548 (C.C.P.A. 1970).

[11] *In re* Rinehart, 531 F.2d 1048, 189 USPQ 143, 147 (C.C.P.A. 1976).

[12] *In re* Lalu, 747 F.2d 703, 223 USPQ 1257, 1258 (Fed. Cir. 1984). *See also In re* Fine, 837 F.2d 1071, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988).

[13] *See also In re* Fritch, 972 F.2d 1260, 23 USPQ 2d 1780, 1783 (Fed. Cir. 1992) (The examiner "can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art *would lead* that individual *to combine* the relevant teachings of the references.") (emphasis added); *In re* Dillon, 919 F.2d 688, 16 USPQ 2d 1897, 1900-01 (Fed. Cir. 1990) (en banc) ("We believe that the PTO has established, through its combination of references, that there is a *sufficiently close relationship* ... to provide the motivation to make such new compositions.") (emphasis added), *cert. denied sub nom.* Dillon v. Manbeck, 500 U.S. 904 (1991). It is unclear whether changing the terminology from "would appear" to "sufficiently close relationship" to "would lead" was intentional. Judge Newman has attempted to alter the requirements of the prima facie case significantly as follows:

The Federal Circuit has further explained, rather "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have reasonable likelihood of success."[14]

It is encumbent on the Examiner to provide sufficient reasoning supporting the obviousness rejection. For example, in *In re Lueders*,[15] the Federal Circuit reversed the obviousness rejection because the Board failed to provide a sufficient basis to support the rejection. The Federal Circuit stated:

> Because there is nothing in this record to teach the use of a visual output, we agree with Lueders that the Board clearly erred in concluding that Hawkins teaches the use of a visual output. ... Each time, the Solicitor answered that there was no such express mention of evidence in the Board's opinion, but argued that because we should review the decision of the Board, not its opinion, we can disregard the lack of express mention of evidentiary support in the opinion as harmless error and find implicit evidence through inductive reasoning. We are unable, however, to find any such implicit support. Indeed, the only implicit support we do find in the record is itself clearly erroneous.[16]

Combined decisions from the Federal Circuit and CCPA indicate that a prima facie case of obviousness is established when the Examiner provides:

1. one or more references
2. that were available to the inventor and
3. that teach
4. a suggestion to combine or modify the references,

> The *prima facie* case, as used in patent examination, means not only that the evidence of the prior art *reasonably allows* the examiner's conclusion of unpatentability, *but also that the prior art compels such a conclusion as a matter of law, if the applicant produces no evidence to rebut it.*

In re Dillon, 16 USPQ 2d at 1908 (Newman, J., dissenting). Any detailed analysis of the inconsistencies of the various opinions on prima facie obviousness is beyond the scope of this book.

[14] Rockwell Int'l Corp. v. United States, 147 F.3d 1358, 47 USPQ 2d 1027, 1033 (Fed. Cir. 1998).

[15] *In re* Lueders, 111 F.3d 1569, 42 USPQ 2d 1481 (Fed. Cir. 1997).

[16] *Id.*, 42 USPQ 2d at 1484.

5. the combination or modification of which would appear to be sufficient to have made the claimed invention obvious to one of ordinary skill in the art.

Accordingly, an Applicant who is able to prove that the Examiner has failed to establish any one of these elements will prevent the prima facie case of obviousness from being established.

Applicants herein provide the following in respect of the Examiner's purported prima facie case of obviousness:

Element 3: References That Teach

The third element of the prima facie case of obviousness requires that the references generally place the needed subject matter supporting the obviousness rejection in the public domain before the date of invention (i.e., generally before the filing date of the application) (*In re* Zenitz, 333 F.2d 924, 142 USPQ 158, 160 (C.C.P.A. 1964)). In this regard, the Federal Circuit has stated that "[t]he test for obviousness is not whether the features of one reference may be bodily incorporated into another reference .... Rather, we look to see whether combined *teachings* render the claimed subject matter obvious." (*In re* Wood, 599 F.2d 1032, 202 USPQ 171, 174 (C.C.P.A. 1979) (emphasis added) (citing *In re* Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549-50 (C.C.P.A. 1969); *In re* Mapelsden, 329 F.2d 321, 322, 141 USPQ 30, 32 (C.C.P.A. 1964)).)

Applicants' Invention

Applicants' application discloses and claims the following:

> 38. A peritoneal dialysis solution comprising at least one amino sugar in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from a patient's blood across the peritoneal membrane of the patient into the solution.

Applicants have already discussed the teachings of the Speck reference and the differences between the Speck reference and Applicants' invention. In particular, the osmolality of the aqueous N-acetylglucosamine solutions in aqua pro injectione of the Speck reference must be adapted to the physiological osmotic pressure. On the other hand, a peritoneal dialysis solution must have a greater osmolarity than the blood to be effective. Thus, the solutions of the Speck reference would not be suitable for performing peritoneal dialysis solution and, if used as such, would fail.

For the foregoing reasons, Applicants respectfully submit that the Speck reference in combination with the knowledge of a person skilled in the art would not suggest to a person skilled in the art the instantly claimed solutions.

Applicants have now shown that the Speck reference is irrelevant and that the knowledge of a person skilled in the art does not add to the teachings of the Speck reference.

Applicants thus respectfully submit that the presently claimed invention may not properly be said to be prima facie obviousness to one of ordinary skill in the art within the meaning of 35 U.S.C. §103 from the teachings of the cited reference.

Applicants respectfully request reconsideration of the Examiner's rejection of Claims 44-47 under 35 U.S.C. §103(a) as being unpatentable over Speck (US Pat. 4,870,061).

Thus, in view of the above, Applicants believe that they have addressed all the issues raised by the Examiner in the Official Action dated February 26, 2003. In so doing, Applicants believe that they have overcome all of the objections and rejections of the Examiner and that the present application is in condition for allowance.

Applicants respectfully request that, should the Examiner have any questions or comments with respect to the response, he should contact Applicants' Representative, Kitt Sinden, collect, at (905) 771-6414 at his convenience prior to issuing a further Office Action or a Notice of Allowance.

Respectfully submitted,

IVOR M. HUGHES

Kitt Sinden

Kitt Sinden
Registration No. 50,188

WKS/jf

Enclosures

1. Requisition for Three-Month Extension of Time
2. Cheque in the amount of U.S. $930.00 payable for Three-Month Extension of Time